

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau(43) International Publication Date
12 February 2004 (12.02.2004)

PCT

(10) International Publication Number
WO 2004/012644 A1(51) International Patent Classification⁷: **A61H 23/04**(21) International Application Number:
PCT/GB2003/003348[GB/GB]; Bourne Court, Ragged Appleshaw, Andover,
Hampshire SP11 9NX (GB). **FOLLETT, Graeme**
[GB/GB]; 55 Hill Road, East Oakley, Basingstoke, Hamp-
shire RG23 7JJ (GB).

(22) International Filing Date: 31 July 2003 (31.07.2003)

(25) Filing Language: English

(74) Agent: **ALLSOP, John, Rowland**; Macleod Allsop,
Bledington Grounds, Bledington, Gloucestershire OX7
6XL (GB).

(26) Publication Language: English

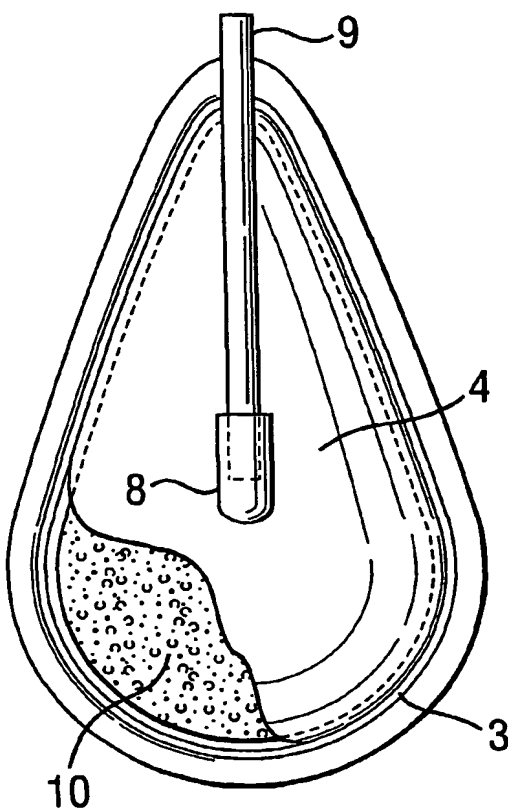
(30) Priority Data:
GB0217996.8 2 August 2002 (02.08.2002) GB(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC,
SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA,
UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.(71) Applicant (*for all designated States except US*): **NO-
VAMEDIX DISTRIBUTION LIMITED [CY/CY]**; Julia
House, 3 Themistocles Dervis Street, P.O. Box 3589,
Nicosia (CY).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **COOK, Gordon**(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: AN INFLATABLE DEVICE FOR USE IN IMPULSE THERAPY

(57) Abstract: The invention relates to impulse therapy and particu-
larly to a device for applying impulse pressure intermittently to a hu-
man foot to enhance blood circulation around the body. In the prior
art impulse pressure is applied by means of an inflatable bladder ap-
plied to the foot. To be effective the bladder has to be filled rapidly
and this produces unacceptable noise during operation. The bladder
in accordance with invention is provided with internal means acting to
dissipate fluid flow with accompanying reduction in fluid flow rates
and consequent noise levels during the pressurisation process.



European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

AN INFLATABLE DEVICE FOR USE IN IMPULSE THERAPY

FIELD OF THE INVENTION

The present invention relates to a device for use in intermittent impulse therapy,
5 particularly but not exclusively for applying intermittent impulse pressure to a
human foot to enhance blood circulation around the body.

BACKGROUND OF THE INVENTION

The use of an inflatable garment applied to a limb or other area of the human body
10 as a means of enhancing blood circulation is a well established medical technique
with proven clinical benefits.

Such a device, known as the A-V Impulse System® is in widespread use and is
designed to apply intermittent impulses to the foot in such a manner as to mimic
15 ambulatory movement which is known periodically to empty the veins of the foot to
drive the blood throughout the body.

The A-V Impulse System® comprises an inflatable bladder being part of or integral
with means in the form of a foot wrap for securing the bladder in the plantar arch of
20 the foot and about the area to be treated.

During use the bladder is filled with a fluid such as air to expand and apply cyclical
force to the plantar arch directed in such a way as to empty the plantar veins of the
foot.

The bladder is held pressurised for a period before releasing the fluid and then the cycle is repeated.

The rate of filling or venting of the bladder may vary from fractions of a second to
5 several seconds according to application, but is dependent upon the bladder volume, fluid flow rate and operating pressure.

To be effective the bladder has to be filled rapidly and the consequent high velocity flow of fluid results in the generation of noise as the fluid passes from the
10 controlling system through the connecting tubing into the bladder.

Noise reduction may be achieved by reducing the fluid flow rate but this is not a feasible remedy because it affects the required rate of pressurisation and desired operating characteristics.

15

SUMMARY OF THE INVENTION

20 It is an object of the present invention to overcome the disadvantages of the prior art by providing the inflatable bladder with an internal volume reducing media or component providing means whereby the same bladder pressurisation is achievable with a lower rate of fluid flow compared with the prior art. A lower rate of fluid flow means lower fluid usage and a reduction in the generation of noise which occurs

when the bladder is being filled. Thus patient comfort is increased while maintaining the effectiveness of the therapy treatment.

According to the present invention there is provided a device for use in applying
5 impulse therapy to a limb of the human body comprising an inflatable bladder,
means for providing intermittent pulses of fluid to the bladder in accordance with a
pre-determined timed sequence of pressure hold and pressure release, means for
securing the bladder around the limb of the human body to apply the bladder to the
area to be treated, characterised in that the bladder is provided with a volume
10 reducing internal component which acts to dissipate the flow of fluid into the
bladder with accompanying reduction in fluid flow rates and noise generated by the
fluid flow during pressurisation of the bladder.

Preferably the internal media is of foam material which may be attached to internal
15 walls of the bladder or fitted loosely within the bladder without attachment.

It may be advantageous to provide the foam with channels for movement of
pressurised air within the bladder.

20 Other features and advantages will now be described with reference to a set of
accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described by way of example with reference to the accompanying drawings wherein:

- 5 Figures 1 and 2 show, in plan and cross-sectional view respectively, a device for applying impulse therapy to a human foot;

Figures 3 and 4 show respectively a side and front view of the device of Figures 1 and 2 as applied to a human foot;

10

Figures 5 and 6 show in plan and cross-sectional view respectively, a device for impulse therapy of the human foot in accordance with the invention;

- 15 Figures 7 and 8 show the a side and front view respectively of the device of Figures 5 and 6 applied to a human foot;

Figure 9 shows the device of Figure 5 and 6 with part of the outer covering cut away to show the internal media of the bladder of the device;

- 20 Figure 10 shows a plan view of the device of Figures 5 and 6 with part of the outer covering of the device cut away to reveal the internal media of the bladder partly-filled by an amount sufficient to occupy the plantar arch of the human foot;

Figure 11 is a cross-sectional view of the device of Figure 9;

25

Figure 12 is a cross-sectional view through the internal media within the bladder of the device of Figure 10 illustrating a preferential profile of the internal media designed to occupy the plantar arch of the foot; and

5 Figure 13 shows a plan view of the device in accordance with the invention with part of the outer covering of the device cut away to reveal the internal media of the bladder provided with air flow channels cut into the media.

10 BEST MODES OF CARRYING OUT THE INVENTION

A device for intermittent impulse therapy to be applied to the human foot is shown in Figures 1, 2, 3 and 4 in accordance with the prior art.

The device comprises an inflatable bladder or pad formed from two films 1, 2 of
15 flexible polymeric material joined at the periphery 3 by, for example, radio frequency (RF) welding to form an essentially sealed pressure vessel or bladder 4.

The bladder 4 is formed integral with a foot wrap 5, see Figure 3, which can be secured, as by velcro action, around the foot 6 as shown in Figures 3 and 4 to hold
20 the bladder 4 generally within the plantar arch 7 of the foot 6 with a void 4 between the bladder 4 and foot arch.

A port connection 8 is sealed to one of the films 1, 2 of the bladder 4 with a connection tube 9 attached to the port 8 to allow air to be admitted and vented
25 from the bladder 4.

As pressurised air is fed to the bladder 4, the bladder 4 is free to expand particularly into the arch 7 of the foot 6 and elsewhere over the bladder surface area, being constrained only by the foot itself and by resistance to outward expansion of the wrap 5 to which the bladder is attached.

During inflation of the bladder 4 air flows through the port connection 8 at high velocity which generates excessive noise caused by the geometry within the flow path of the air and by pressurised air impinging directly on to the inner wall 5 of the bladder 4 opposite the port connections 8.

It is to the elimination of the excessive noise caused by the movement of pressurised air as described that the present invention is directed and in this way to improve the performance of the impulse therapy device and enhance patient fit up, comfort and well-being.

The improved impulse therapy device in accordance with the invention is illustrated in Figures 5 through 13.

In these embodiments the device itself is constructed in accordance with the prior art as discussed with reference to Figures 1 through 4 with the exception that in accordance with the invention the bladder 4 is provided with an internal media 10 in the form preferably of a foam, gel or fluid reservoir which reduces the internal volume of the bladder. The internal media in accordance with the invention may be

attached to one or other, or both, films of the bladder 4. Alternatively, it may be freely inserted within the bladder 4.

The internal media acts to dissipate the flow of fluid within the bladder thus
5 reducing noise and also the amount of fluid necessary to achieve the required rate of pressurisation.

The improved bladder 4 of the impulse therapy device in accordance with the invention may be constructed by forming the internal media 10 by an injection
10 moulding process, either applied to bladders formed in accordance with the prior art or as part of multi-shot process to manufacture a bladder with an internal media by automated means, using for example a thermoplastic elastomer polymer together with a foaming technique to produce an integral cellular construction as the internal media.

15

The improved impulse therapy device in accordance with Figures 5 and 6 is shown applied to a human foot in Figures 7 and 8 in like manner as with the conventional impulse therapy device illustrated in Figures 3 and 4.

20 Whereas in the Figure 5 embodiment the media 10 fills the entire space within the bladder 4 in alternative form the media may be appropriately profiled 10' within the bladder such that when the device is applied to the foot the media conforms to the plantar arch 7, as illustrated with reference to Figures 10, 11 and 12.

The Internal media 10 may be constructed from either a closed cell or open cell form according to the desired benefits of internal bladder volume reduction consistent with suitable air flow either immediately through and within the media, with channels 11 formed or cut into the media as shown in Figure 13 or over and
5 around the media.

The inclusion of an internal media within the bladder of the Impulse therapy device as described above and in accordance with the invention, has significant actual and perceived implications for user comfort leading to improved product acceptance,
10 compliance and clinical results.

In addition, a specific improvement has been observed when using the improved impulse therapy device in accordance with the invention fitted more loosely than is recommended with the prior art device as described with reference to Figures 1
15 through 4. Without inclusion of the internal media within the bladder it is necessary to fit the garment to the foot relatively snugly to avoid over-inflation and thus excessive air consumption. A disadvantage of such a fit-up is to cause a static force to be applied to the limb throughout the uninflated phase of applied impulse pressure thereby to some extent hindering re-priming of the veins of the foot
20 following evacuation.

With the inclusion of the internal media the necessity to tighten the device as snugly as previously is reduced and consequently the static force on the foot is lessened allowing superior re-priming of the veins of the foot to occur.

25

CLAIMS

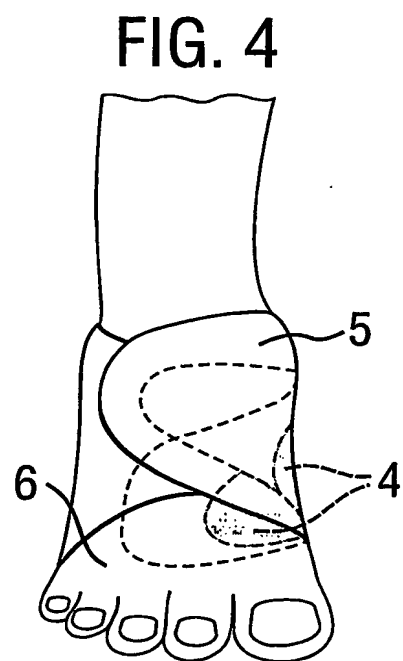
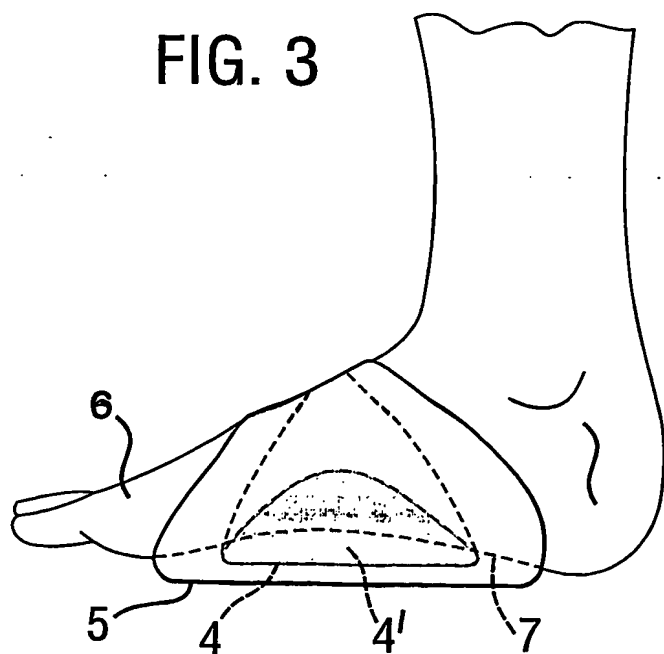
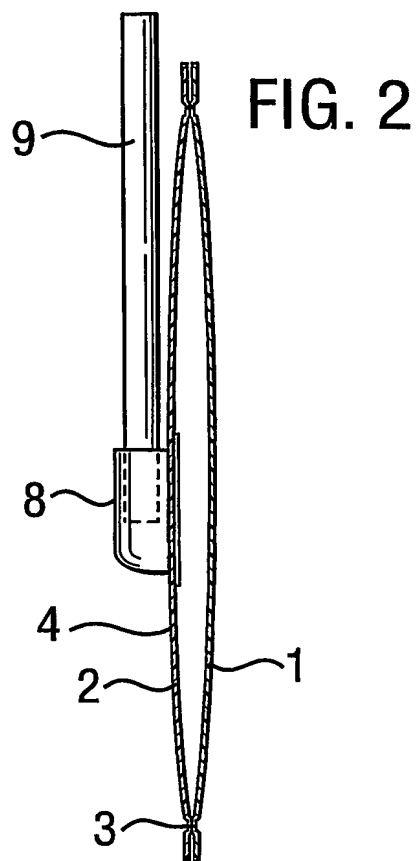
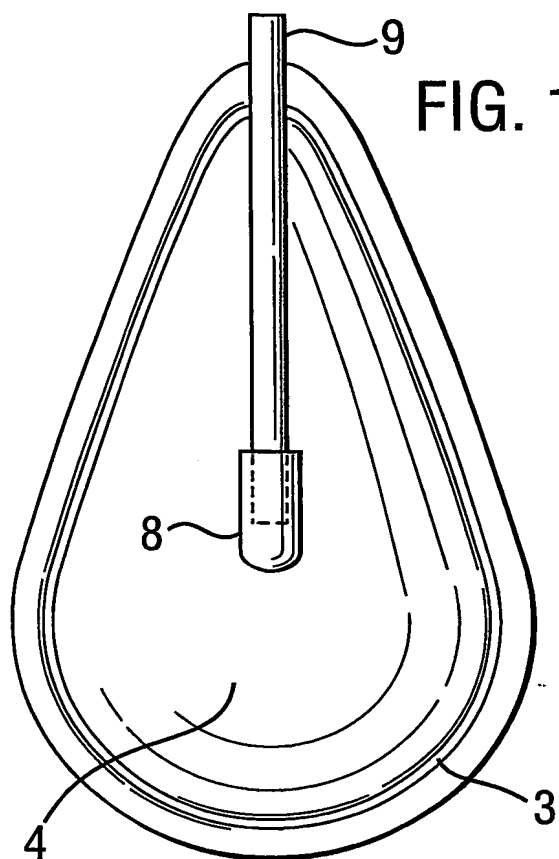
1. A device for use in applying impulse therapy to a limb of the human body comprising an inflatable bladder, means for providing intermittent pulses of fluid to the bladder in accordance with a pre-determined timed sequence of pressure hold and pressure release, means for securing the bladder around the limb of the human body to apply the bladder to the area to be treated, characterised in that the bladder is provided with a volume-reducing internal component which acts to dissipate the flow of fluid into the bladder with accompanying reduction in fluid flow rates and noise generated by the fluid flow during pressurisation of the bladder.
2. A device as claimed in Claim 1 wherein the internal component is of foam material.
3. A device as claimed in Claim 1 wherein the internal component is a gel.
4. A device as claimed in Claim 1 where in the internal component is a fluid reservoir.
5. A device as claimed in Claim 2 wherein the foam is attached to one or both walls of the bladder.
6. A device as claimed in Claim 5 wherein the foam is provided with air flow channels.

7. A device for use in applying impulse therapy to a limb of the human body comprising a flexible pad having an inflatable interior, means for providing intermittent impulses of fluid to the inflatable interior in accordance with a predetermined timed sequence of pressure hold and pressure release,
- 5 means for securing the flexible pad around the limb of the human body to apply the pad to the area to be treated, characterised in that the inflatable interior is filled or partially filled with a cellular component providing means for reducing fluid flow rates and noise during pulsed pressurisation of said inflatable interior of the flexible pad.
- 10
8. A device as claimed in claim 7 wherein the cellular component acting as a sound absorbing media, is formed during construction of the bladder by an injection moulding process.
- 15 9. A device as claimed in claim 7 when the cellular component is a foam material.
10. A device for use in applying impulse therapy to a limb of the human body comprising a flexible pad having an inflatable chamber, means for providing
- 20 intermittent pulses of fluid to the inflatable chamber in accordance with a predetermined timed sequence of pressure hold and pressure release, means for securing the flexible pad around the limb of the human body to apply the flexible pad to the area to be treated, characterised in that the inflatable chamber is provided with means for varying the internal

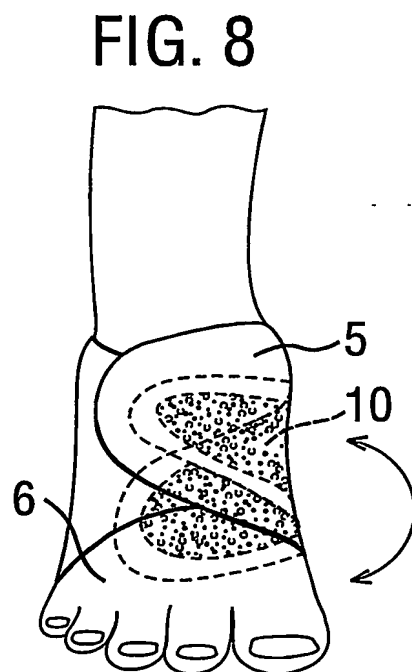
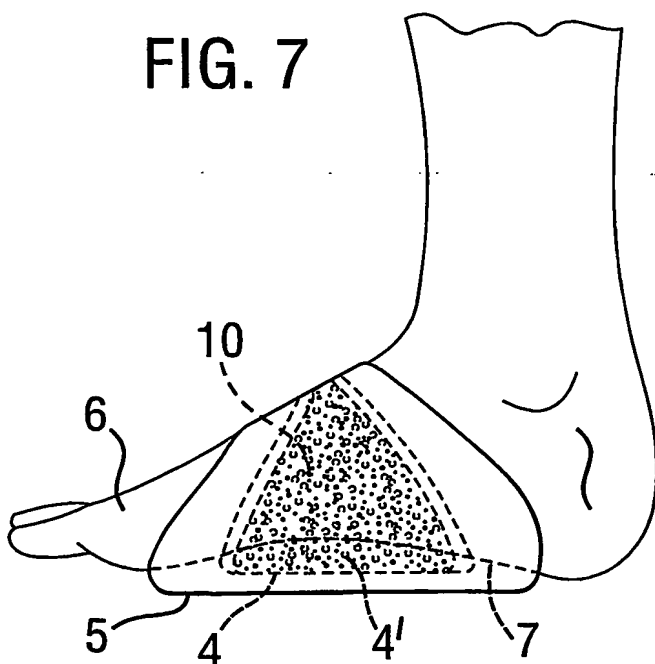
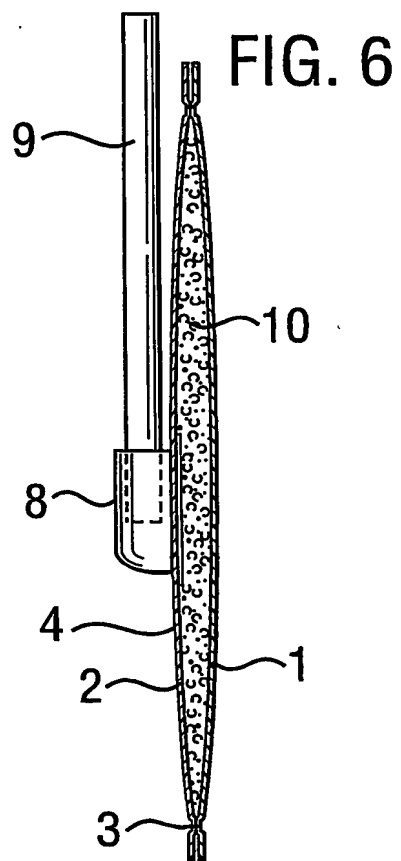
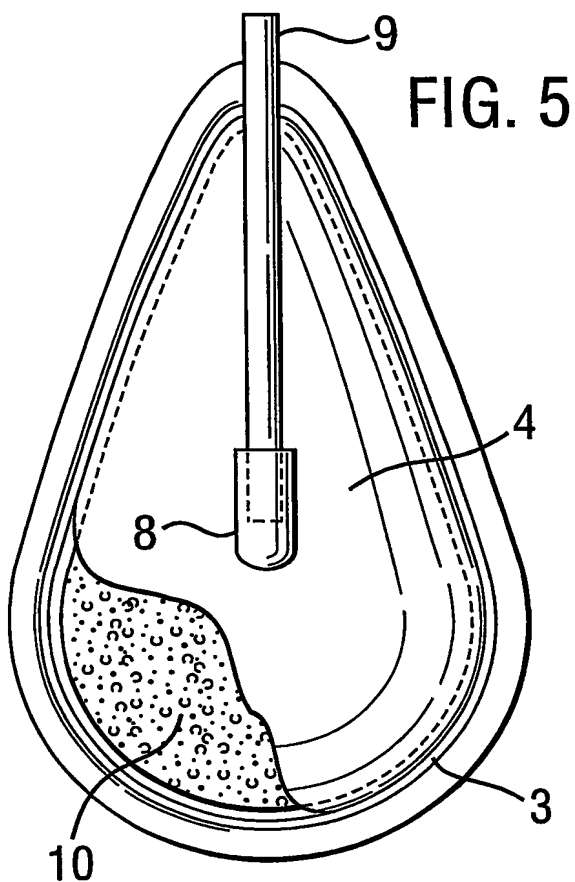
volume of the chamber thereby to control fluid flow rates and generation of noise during pressurisation of the chamber.

11. A device as claimed in claim 10 wherein said means for varying the internal
5 volume of the chamber is a gel or liquid.
12. A device for use in applying impulse therapy to a limb of the human body comprising a flexible pad having an internal chamber adapted to inflate when supplied with fluid at a predetermined pressure, adjustable securing
10 means for securing the pad around the limb of a human body at an adjustable pressure to apply the inflatable chamber to the area to be treated, and means within the chamber adapted to maintain the required pressurisation of the chamber with reduced rates of fluid flow and applied
15 adjustable pressure of the pad against the limb by said securing means.

1/4



2/4



3/4

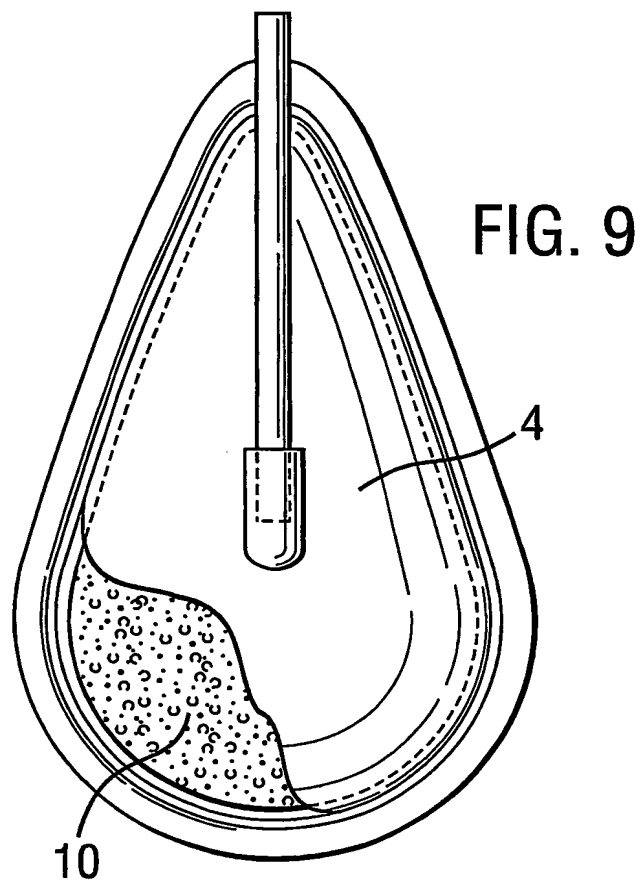
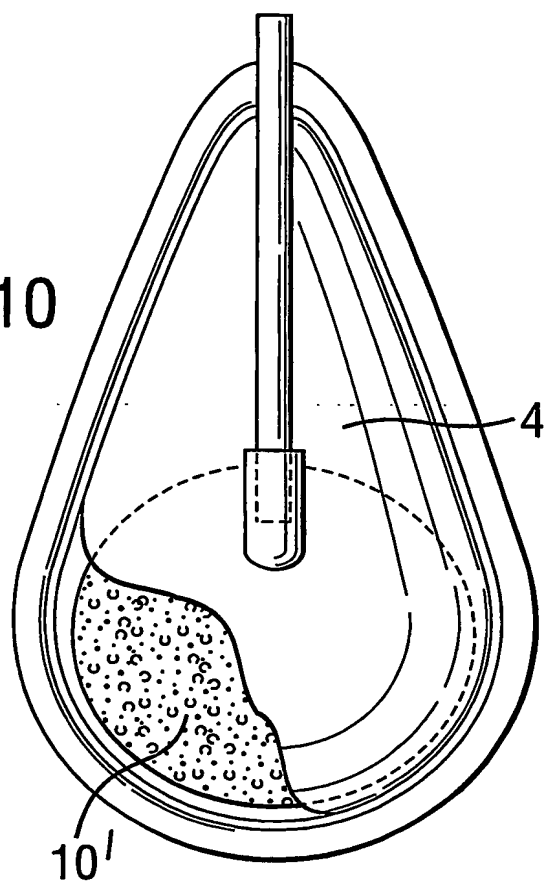
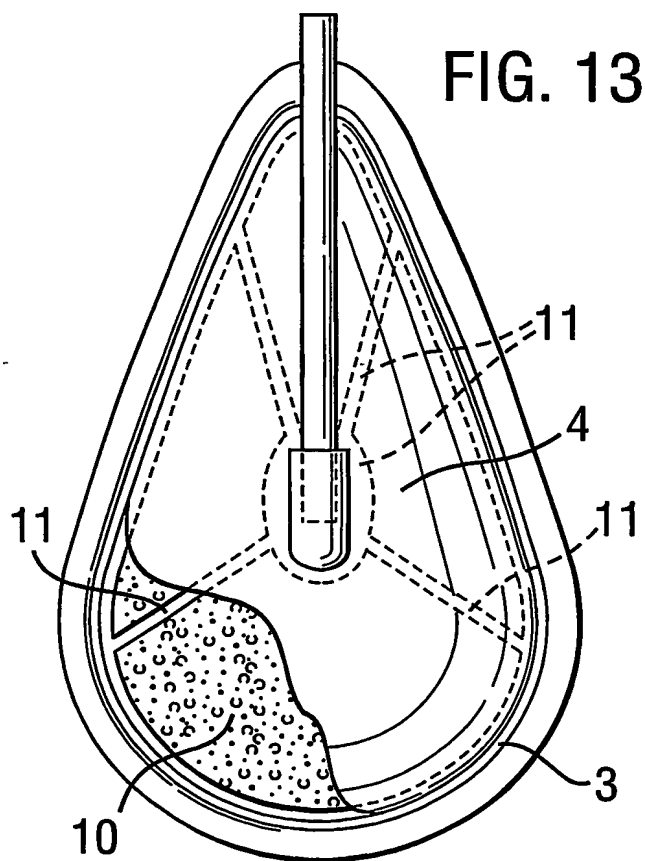
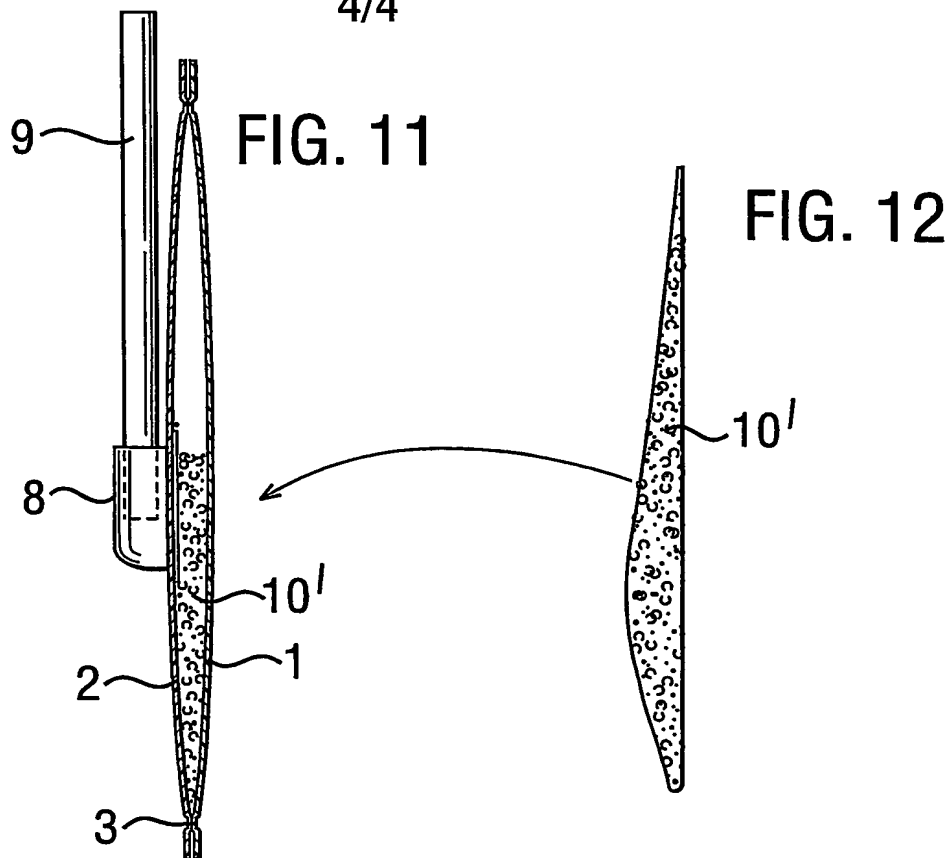


FIG. 10



4/4



INTERNATIONAL SEARCH REPORT

International application No
PCT/GB 03/03348

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61H23/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61H A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 01770 A (AIRCRAFT INC) 19 January 1995 (1995-01-19) page 11, line 18 -page 20, line 19	1,2
Y		5-9
Y	US 6 425 195 B1 (DONZIS BYRON A) 30 July 2002 (2002-07-30) column 6, line 19 -column 7, line 1 column 8, line 1 - line 38	5,6,8
X	WO 01 47464 A (AIRCRAFT INC) 5 July 2001 (2001-07-05) the whole document	1,4,10, 12
Y		7,9
X	WO 02 02181 A (EMBRO CORP) 10 January 2002 (2002-01-10) page 12, line 8 -page 14, line 28	1,2,5,7, 9,12
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *Z* document member of the same patent family

Date of the actual completion of the international search

12 December 2003

Date of mailing of the international search report

02/01/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Millward, R

INTERNATIONAL SEARCH REPORT

Internatio pplication No
PCT/GB 03/03348

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 496 262 A (JOHNSON JR GLENN W ET AL) 5 March 1996 (1996-03-05) the whole document	1,2,4
A		7,9,10
A	US 6 228 044 B1 (BUREK PAUL P ET AL) 8 May 2001 (2001-05-08) the whole document	3,8,10, 11

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat. Application No
PCT/GB 03/03348

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9501770	A	19-01-1995	AT 241331 T AU 7219194 A DE 69432750 D1 DK 707468 T3 EP 0707468 A1 JP 9502365 T WO 9501770 A1 US 5588955 A	15-06-2003 06-02-1995 03-07-2003 22-09-2003 24-04-1996 11-03-1997 19-01-1995 31-12-1996
US 6425195	B1	30-07-2002	US 5235715 A US RE37705 E1 AU 2522088 A CA 1336316 C WO 8902363 A1 US 4874640 A	17-08-1993 21-05-2002 17-04-1989 18-07-1995 23-03-1989 17-10-1989
WO 0147464	A	05-07-2001	US 6592534 B1 AU 3083401 A CA 2398023 A1 EP 1250115 A1 WO 0147464 A1	15-07-2003 09-07-2001 05-07-2001 23-10-2002 05-07-2001
WO 0202181	A	10-01-2002	US 6551280 B1 AU 8045501 A CA 2413787 A1 EP 1294433 A1 WO 0202181 A1 US 2003191437 A1	22-04-2003 14-01-2002 10-01-2002 26-03-2003 10-01-2002 09-10-2003
US 5496262	A	05-03-1996	NONE	
US 6228044	B1	08-05-2001	EP 1148852 A2 WO 0040202 A2 US 2002095105 A1	31-10-2001 13-07-2000 18-07-2002